

US Serial No. 10/645248
Page 9 of 17

Remarks:

Regarding the rejection of claims 1-8, and 13-26 under 35 USC 102(e) in view of US 6080387 to Zhou, et al. (hereinafter "Zhou"):

The applicant traverses the rejection of the claims in view of the reference to Zhou, particularly in view of the foregoing amendments to the claims.

With regard to Zhou, the applicant points out that a reading of Zhou's specification quickly reveals to the reader that the invention of Zhou is based on a composition which includes the following constituents (see Zhou, col. 3):

The aerosol formulation comprises an antimicrobial composition that is mixed with a propellant. The composition 15
has the following ingredients:

- (a) an anionic polymer or prepolymer;
- (b) a quaternary ammonium compound, the components
 (a) and (b) combining to form an antimicrobially effective complex;
- (c) at least one water-soluble or dispersible organic solvent having a vapor pressure of at least 0.001 mm Hg
 at 25° C., said at least one organic solvent present in a solubilizing—or dispersion—effective amount;
- (d) an effective amount of a propellant; and 20
- (e) the remainder, water.

Additional adjuncts in small amounts such as buffers, fragrances, dyes and the like can be included to provide desirable attributes of such adjuncts. 25

Therein is clearly indicated that amongst essential constituents are (a) and (b) which "... the components combining to form an antimicrobially effective complex.." This is further supported by Zhou in his statement at column 4 wherein he indicates that:

The antimicrobial composition is preferably prepared by mixing effective amounts of the anionic component and the quaternary ammonium compound in water with agitation. A water miscible solvent and/or dispersing/emulsifying/wetting agent is preferably added before the two main

As well as at column 5 where he indicates that:

US Serial No. 10/645248

Page 10 of 17

part of the invention. The most preferred range of 5:1 to 1:5 appears to result in an aesthetically pleasing film which has 15 excellent residual antimicrobial efficacy, as well as disinfectancy. This also seems to imply that, in the cured film/ residue, there may actually not be complete ion pairing between the quaternary ammonium compound and the anionic sites in the anionic polymer, since the quaternary 20 ammonium active sites are available for residual microbial kill, although there is clearly an interaction between the two components. Again, the mechanism of the film/residue is not

And later at column 5 Zhou unequivocally "critically" identifies the role of the quaternary ammonium compound, or surfactant as being the sole agent responsible for providing a bacteriostatic/disinfectant benefit wherein he recites:

A critical second component of the invention is a quaternary ammonium compound, or surfactant. These types of 40 surfactants are typically used in bathroom cleaners because they are generally considered "broad spectrum" antimicrobial compounds, having efficiency against both gram positive (e.g., *Staphylococcus* sp.) and gram negative (e.g., *Escherichia coli* or *Klebsiella* sp.) microorganisms. Thus, the quaternary ammonium surfactant, or compounds, are incorporated for bacteriostatic/disinfectant purposes and should be present in amounts effective for such purposes. 45

From the foregoing, it is made unequivocally clear that Zhou's compositions require this "(a)+(b) complex" in order to provide an antimicrobial benefit, and particularly in view of the foregoing passages of Zhou, that the quaternary ammonium compound provides the antimicrobial benefit. Thus it is clear to see that the both (a) and (b), (..but especially the quaternary ammonium compound..) are (i) essential constituents, and (ii) the quaternary ammonium compound provides the antimicrobial benefit. Thus the (a)+(b) complex define the operative mechanism for providing an antimicrobial benefit according to Zhou.

In contrast to the above, by even a simple review of the present applicant's specification, applicant's claimed compositions do not require either (a) or (b), nor the "(a)+(b) complex" in order to provide an antimicrobial benefit. Thus, *prima facie*, applicant's invention which provides effective antimicrobial efficacy absent the "(a)+(b) complex"

US Serial No. 10/645248
Page 11 of 17

is a clear indication that a different operative mechanism is at work, and thus is *prima facie* both unanticipated and nonobvious over the Zhou reference. (For example, applicant's Ex. 30 demonstrates a 6 log₁₀ reduction of Poliovirus absent both of Zhou's (a) and or (b), and none of applicant's examples illustrate Zhou's (b) polymers). The Examiner's assertions to the contrary are unsupported by the Zhou reference for the reasons outlined above. At best, the Examiner's selective reading of Zhou appears to be a "hindsight reconstruction" of the applicant's claimed invention which is however impermissible. The Examiner is reminded that in In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992), the Federal Circuit stated:

"It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. In re Gorman, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). This court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." (quoting In re Fine, 837 F.2d at 1075, 5 USPQ2d at 1600)

See also W.L. Gore & Associates, Inc. v. Garlock, Inc. 220 USPQ 303 (CAFC, 1983); In re Mercier 185 USPQ 774, 778 (CCPA, 1975); In re Geiger 2 USPQ2d 1276 (CAFC, 1987)

In this paper the applicant has amended the independent claims present, as well as added new claims, which are believed to patentably distinguish over the Zhou reference. The amended independent claims include a limitation which reads "...which aforesaid alkaline aqueous alcohol constituents are sufficient to provide at least 1 log₁₀ of Poliovirus reduction in the absence of further constituents ..." which recognizes that applicant's compositions are effective in providing excellent efficacy against Poliovirus utilizing a system, viz., an aqueous-alcohol mixture within a specific pH range, and that such system is sufficient to provide effective control of the Poliovirus. Support for this new limitation may be found in applicant's specification, inter alia, at Fig. 1 of applicant's specification and the related description in applicant's specification.

US Serial No. 10/645248
Page 12 of 17

Applicant's claimed system of aqueous-alcohol mixture within a specific pH range is not demonstrated or at all suggested by Zhou's very different system which necessarily comprises Zhou's two essential constituents, here his "a) anionic polymer or prepolymer" and b) quaternary ammonium surfactant, both of which are necessary to form Zhou's polymer complex which is used to provide his antipathogenic benefits. These currently presented claims exclude "film-forming polymers" which patentably distinguish over Zhou's compositions, and without which, Zhou's compositions would not be effective. Further, as it is also clear that the applicant's invention and its success in the eradication of undesirable pathogens and fungi are based on a system of constituents which are distinguishable from Zhou's "(a)+(b)" combination, applicant's currently claimed compositions should also be considered nonobvious thereover.

Accordingly, in view of the foregoing remarks, reconsideration of the propriety of the rejection under 35 USC 102(e) is requested, and it is further requested that the rejection be withdrawn.

Regarding the rejection of claims 1-8, and 13-26 under 35 USC 102(b) and 35 USC 103(a) in view of US 3282776 to Kitzke (hereinafter simply "Kitzke"):

The applicant respectfully traverses the Examiner's rejection of the claims as being "anticipated" or "obvious" in view of the Kitzke reference.

Prior to discussing the relative merits of the Examiner's rejection, Applicant points out that unpatentability based on "anticipation" type rejection under 35 USC 102(b) requires that the invention is not in fact new. See *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302, 36 USPQ2d 1101, 1103 (Fed. Cir. 1995) ("lack of novelty (often called 'anticipation') requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee"). Anticipation requires that a *single reference* [emphasis added] describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in

US Serial No. 10/645248
Page 13 of 17

the prior art. See, *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

The principle of "inherency," in the law of anticipation, requires that any information missing from the reference would nonetheless be known to be present in the subject matter of the reference, when viewed by persons experienced in the field of the invention. However, "anticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation, [or the reference] cannot inherently anticipate the claims." *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 [62 USPQ2d 1865] (Fed. Cir. 2002); *Hitzeman v. Rutter*, 243 F.3d 1345, 1355 [58 USPQ2d 1161] (Fed. Cir. 2001) ("consistent with the law of anticipation, an inherent property must necessarily be present in the invention described by the count, and it must be so recognized by persons of ordinary skill in the art"); *In re Robertson*, 169 F.3d 743, 745 [49 USPQ2d 1949] (Fed. Cir. 1999) (that a feature in the prior art reference "could" operate as claimed does not establish inherency).

Thus when a claim limitation is not explicitly set forth in a reference, evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co.*, 948 F.2d at 1268. It is not sufficient if a material element or limitation is "merely probably or possibly present" in the prior art. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 [63 USPQ2d 1597] (Fed. Cir. 2002). See also, *W.L. Gore v. Garlock, Inc.*, 721 F.2d at 1554 (Fed. Cir. 1983) (anticipation "cannot be predicated on mere conjecture respecting the characteristics of products that might result from the practice of processes disclosed in references"); *In re Oelrich*, 666 F.2d 578, 581 [212 USPQ 323] (CCPA 1982) (to anticipate, the asserted inherent function must be present in the prior art).

The undersigned also reminds the Examiner that the determination of obviousness under § 103(a) requires consideration of the factual inquiries set forth in *Graham v. John Deere*

US Serial No. 10/645248
Page 14 of 17

Co., 383 U.S. 1 [148 USPQ 459] (1966): (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness. *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1368, 67 USPQ2d 1649, 1653 (Fed. Cir. 2003). There must be some suggestion, teaching, or motivation arising from what the prior art would have taught a person of ordinary skill in the field of the invention to make the proposed changes to the reference. *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). But see also *KSR International Co. v. Teleflex Inc.*, 82 USPQ2D 1385 (U.S. 2007).

A methodology for the analysis of obviousness was set out in *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher."

It must also be shown that one having ordinary skill in the art would reasonably have expected any proposed changes to a prior art reference would have been successful.

Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1207, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); *In re O'Farrell*, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988); *In re Clinton*, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

US Serial No. 10/645248
Page 15 of 17

Turning now to Kitzke, a reading of that prior art document quickly teaches the reader that the component of Kitzke's composition which provides disinfection is the necessary "Quaternary" compounds. Kitzke recites at col. 7:

(d) *Quaternary.*—Although a vast array of germicides are available commercially today including numerous quaternary compounds the compositions of the invention are limited to a specific class of quaternary compounds described in detail below. These compounds are unexpectedly well suited for use in the surface disinfecting-air sanitizing compositions of the invention by reason of their preeminent bactericidal properties. These quaternaries have been found to provide unobvious and unexpected surface disinfecting and air sanitizing performance when used in the compositions of the invention. 10 15

The need for the quaternary surfactants are reinforced by a review of the results reported on Kitzke's "Table 1" and "Table 3" each of which clearly identify the need for a pair of quaternary ammonium compounds needed to provide a disinfecting benefit to Kitzke's aerosol compositions. Thus, from the foregoing it is clear that Kitzke neither "anticipates" the applicant's currently claimed compositions, or that applicant's currently claimed compositions could be considered "obvious" from the Kitzke reference and especially the compositions taught therein. Kitzke unequivocally teaches his pair of quaternary ammonium compounds as an essential constituent in order to provide a disinfecting benefit, the current applicant's teach a different system which provides as surprisingly effective benefit in controlling unwanted microorganisms.

In view of the foregoing amendments to the claims and remarks presented, withdrawal of all grounds of rejection and allowance of the claims to grant is requested.

Early issuance of a *Notice of Allowability* is requested.

US Serial No. 10/645248
Page 16 of 17

Should the Examiner believe that telephonic communication will advance the prosecution of the present application they are invited to telephone the undersigned at their convenience.

PETITION FOR A ONE-MONTH EXTENSION OF TIME

The applicants respectfully petition for a one-month extension of time in order to permit for the timely entry of this response. The Commissioner is hereby authorized to charge the fee to Deposit Account No. 14-1263 with respect to this petition.

CONDITIONAL AUTHORIZATION FOR FEES

Should any further fee be required by the Commissioner in order to permit the timely entry of this paper, including any extension of time fees, the Commissioner is authorized to charge any such fee to Deposit Account No. 14-1263.

Respectfully Submitted;

Andrew N. Parfomak, Esq.

Reg. No. 32,431

Norris, McLaughlin & Marcus, PC
875 Third Avenue, 18th Floor
New York, NY 10022

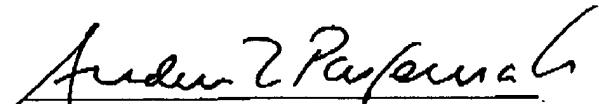
Date:

Tel: 212 808-0700

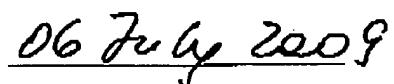
US Serial No. 10/645248
Page 17 of 17

CERTIFICATION OF TELEFAX TRANSMISSION:

I hereby certify that this paper and all attachments thereto is being telefax transmitted to the US Patent and Trademark Office to telefax number: 571 273-8300 on the date shown below:



Andrew N. Parfomak



Date:

C:\ANPCMB\102792\158\Amendment07.doc